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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,684	02/18/2004	Mark W. Kroll	A04P1016	5251

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/782,684	KROLL, MARK W.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,13-20 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,13-15,19,20,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 May 2007 has been entered. Claims 10, 12 and 21-22 are cancelled; claims 1-9, 11, 13-20 and 23-25 are pending.

Claim Objections

2. In view of the amendments received 03 May 2007, the examiner withdraws the objection to claim 18.

Response to Arguments

3. Applicant's arguments with respect to claims 1, 23 and 25 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2, 4-6, 8-9, 11, 13-15, 19-20, 23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Lade et al (U.S. 6,719,701). Regarding claims 1, 8-9 and 20, Lade discloses, (Figure 5; col. 8, lines 61-67) "At step 405, the monitor (10) monitors the heart rate and other physiologic signals until a storage-triggering event is detected at step 410. Data is then stored in memory (94) at step 420, and at step 425 the data and triggering event may be further analyzed in order to confirm that vasovagal syncope is suspected to be occurring or about to occur." Lade further discloses, (col. 6, lines 23-27) "The memory (94) is capable of storing large amounts of digitized physiological data in designated blocks of memory until such data is permanently downloaded and cleared by a physician." Therefore, the examiner considers memory (94) to be a temporary memory, as compared to permanent downloading and storage. The examiner considers Lade's method to comprise monitoring cardiac rhythm through an implantable medical device (implantable monitor 10, Figure 1; step 405); evaluating the cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise (step 410); and controlling the storing and recording of diagnostic data associated with the cardiac rhythm such that no diagnostic data is stored in the temporary memory until it has been determined that a cardiac arrhythmia is likely to arise (step 420).

6. Regarding claims 23 and 25, the examiner considers the monitor (10) to be a device operative to monitor cardiac rhythm, as well as means for monitoring cardiac

rhythm through the implantable medical device and means for evaluating the cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise; memory (94) to be a temporary memory operative to store diagnostic medical data, as well as means for temporarily storing data; and external device (102; Figure 2) to be a long-term memory operative to record the diagnostic medical data stored in the temporary memory (via telemetry link 104), as well as means for recording the temporarily stored data. Lade further discloses microcontroller (60; col. 7-16) for controlling the functions of the implantable device; the examiner considers this to be a risk-based diagnostic data controller capable of operating the device in the claimed manner, as well as means for controlling the storing and recording of diagnostic data within the means for temporarily storing data and means for recording the temporarily stored data in the claimed manner.

7. Regarding claim 2, the examiner considers the trigger condition disclosed by Lade to be periods of time wherein there is an elevated risk of an arrhythmia that are identified by the implantable system. The examiner therefore considers the system of Lade to be storing the data in the temporary memory only during the period of time wherein there is an elevated risk of an arrhythmia.

8. Regarding claim 4, Lade discloses (col. 12, lines 11-19) detection of atrial and ventricular events, including ventricular fibrillation. Since Lade further discloses, in previously cited paragraphs, identifying within sensed signals "acquiring and storing data leading up to and during a detected arrhythmia or syncopal event," the examiner

considers Lade's system to disclose identifying periods of time wherein there is an elevated risk of ventricular fibrillation.

9. Regarding claims 5 and 11, Lade discloses, (col. 12, lines 45-57) "The timing intervals between sensed events (e.g. P-waves, R-waves, and depolarization signals associated with fibrillation which are sometimes referred to as "F-waves" or "Fib-waves") are then classified by the arrhythmia detector (77) by comparing them to a predefined rate zone limit (e.g. bradycardia, normal, low rate ventricular tachycardia, high rate ventricular tachycardia, and fibrillation rate zones) and various other characteristics (e.g. sudden onset, stability, physiologic sensors, and morphology, etc.), in order to determine the type of remedial therapy that is needed (e.g. bradycardia pacing , anti-tachycardia stimulation, cardioversion shocks or defibrillation shocks, collectively referred to as "tiered therapy")." Though Lade discloses assignment of fibrillation based on the above characteristics in order to select a treatment option, the examiner considers this method to be capable of being used along with the method as disclosed in Figure 5, for temporary storage of patient data.

10. Regarding claims 6 and 15, the examiner considers the flow chart in Figure 5 to show a method that includes deactivating the storing of diagnostic data in the temporary memory in arrhythmia is not confirmed, or if no further episodes of ventricular tachycardia are detected. The system, at step 425, loops back to monitoring cardiac rhythm data if an arrhythmic event is not confirmed.

11. Regarding claim 19, Lade discloses (col. 14, lines 1-5) the use of IEGM and event records.

12. Regarding claim 13, Lade discloses (col. 7, lines 31-35) "a trigger event may be the detection of a heart rate exceeding an upper rate limit, a heart rate lower than a lower rate limit, or a change in heart rate exceeding a given number of beats per minute."

13. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lade et al (U.S. 6,719,701) in view of Sweeney et al (U.S. 6,400,982). Lade discloses the claimed invention except for monitoring heart rate variability and identifying periods of time with reduced heart rate variability. Sweeney however discloses (col. 7, lines 52-68; col. 8, lines 1-3) a method for use with an implantable system for predicting cardiac arrhythmias, which includes the steps of sensing cardiac parameters and predicting an arrhythmia based on arrhythmic triggers or markers. Some of these triggers include abnormal heart rate variability. Though Sweeney does not mention recording the

diagnostic data, the invention can be used (col. 7, lines 48-51) with apparatus that include programmers and recorders. Further Sweeney and Lade both disclose diagnostic systems for use with cardiac rhythm management. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lade's diagnostic data recorder with Sweeney's heart rate variability detection in order to provide a parameter for recording that uses heart rate as a predictor for arrhythmia.

16. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lade et al (U.S. 6,719,701). Lade discloses the claimed invention except for a fixed period of time of at least nine months, and a predetermined number of heartbeats within the range of one to three beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fixed period of time of at least nine months, and to provide a predetermined number of heartbeats within the range of one to three beats, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Allowable Subject Matter

17. Claims 16-18 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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